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APPLICATION NO.	I	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,574		01/10/2002	Jian Ni	PF375P1D1	7011
22195	7590	01/06/2004		EXAM	XAMINER
		E SCIENCES INC	O HARA, EILEEN B		
9410 KEY ' ROCKVILI				ART UNIT	PAPER NUMBER
,				1646	
				DATE MAILED: 01/06/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)					
	10/041,574	NI ET AL.					
Office Action Summary	Examiner	Art Unit					
	Eileen O'Hara	1646					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status							
1) Responsive to communication(s) filed on 15 Oc	<u>ctober 2003</u> .						
2a)⊠ This action is <b>FINAL</b> . 2b)□ This a	action is non-final.						
	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims		·					
4) Claim(s) 25-126 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) is/are allowed.  6) Claim(s) 25-126 is/are rejected.  7) Claim(s) is/are objected to.  8) Claim(s) are subject to restriction and/or election requirement.							
Application Papers							
9) The specification is objected to by the Examiner.  10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correcti	on is required if the drawing(s) is obj	ected to. See 37 CFR 1.121(d).					
11) The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.					
Priority under 35 U.S.C. §§ 119 and 120							
<ul> <li>12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a)  All b)  Some * c) None of:</li> <li>1.  Certified copies of the priority documents have been received.</li> <li>2.  Certified copies of the priority documents have been received in Application No</li> <li>3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> <li>13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet.</li> <li>37 CFR 1.78.</li> <li>a) The translation of the foreign language provisional application has been received.</li> <li>14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.</li> </ul>							
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.	5) Notice of Informal Pa	(PTO-413) Paper No(s) atent Application (PTO-152)					

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#### **DETAILED ACTION**

1. Claims 25-126 are pending in the instant application. Claims 25-32, 44, 45, 50-57, 68, 69, 73-80, 92, 93, 98-105, 116, 117, 121, 125 and 126 have been amended, claims 1, 14 and 20 have been canceled as requested by Applicant in the Paper filed October 15, 2003.

All claims are currently under examination.

## **Priority**

2. Applicants' amendment to the specification to update the status of Application 09/527,236 is acknowledged.

## Objection to Specification

3. The objections to the specification are withdrawn in view of Applicants' amendment.

### Information Disclosure Statement

4. References BD and BE of the IDS filed May 7, 2003 that were included in the response filed Oct. 15, 2003 have been considered and a duplicate initialed IDS is included in this action.

#### Withdrawn Rejections

- 5.1 The rejection of claims under obviousness-type double patenting is withdrawn in view of Applicants' terminal disclaimer filed Oct. 15, 2003.
- 5.2 The rejection of claims under 112 § 1 for the biological deposit is withdrawn in view of Applicants' statement regarding permanence and availability of deposited plasmids filed Oct. 15, 2003 which serves to perfect the required deposit.
- 5.3 The rejection of claims under 112 § 2 is withdrawn in view of Applicants' amendment.

# Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 6. Claims 25-33, 35-37, 41, 44-58, 60, 61, 65, 68-81, 83-85, 89, 92-106, 108, 109, 113, 116-122 and 124-126 remain rejected under 35 U.S.C. 102(e) as being anticipated by Deen et al., U.S. Patent No. 6,013,476, for reasons of record in the previous office action at pages 9-11, and below.

Applicants traverse the rejection and assert that the provisional application 60/041,796 (the '796 application) is the only Deen et al. disclosure which is relevant for the purposes of analysis under 35 U.S.C. 102(e), and further assert that the '796 application provides only a limited amount of amino acid sequence information, an amino acid sequence of 102 contiguous amino acids deduced from a partial cDNA, and that the entire amino acid sequence set forth in Figure 1 of the '796 application corresponds to 15.6% of the full-length amino acid sequence of 655 amino acid residues later disclosed in the '382 application. Applicants contend that the partial amino acid sequence provided by the '796 application is insufficient to allow one of skill in the art to appreciate the structure of the full-length polypeptide of the instant application, as discussed on pages 18-21 of the response, and the disclosure of the '796 application does not

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meet the requirements of 35 USC §§ 101 and 112, first paragraph, and therefore is insufficient to anticipate the instant claims.

The Examiner agrees with Applicants that the 60/041,796 disclosure is the only Deen et al. disclosure which is relevant for the purposes of analysis under 35 U.S.C. 102(e). As discussed in the previous office action at page 10, provisional 60/041,769 disclosed a polypeptide sequence that is identical to amino acids -14 to 48 and 51-84 of SEQ ID NO: 2 of the instant application. However, Applicants' arguments regarding that the '796 application is insufficient to allow one of skill in the art to appreciate the structure of the full-length polypeptide of the instant application, and that the disclosure of the '796 application does not meet the requirements of 35 USC §§ 101 and 112, first paragraph, have been fully considered but are not deemed persuasive. Under 35 U.S.C. 102(e), a person shall be entitled to a patent unless - (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language. Therefore, in order for a disclosure to be anticipatory under 35 USC § 102 (e), the invention need only be described in a prior application; the disclosure need not demonstrate utility, or be enabled for using the protein. The structure and function of the full-length protein is not relevant, as the instant claims are drawn to antibodies to the polypeptide of SEQ ID NO: 2 of the instant

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invention, and portions of this polypeptide were disclosed in the '796 application. The instant claims are drawn to antibodies to portions of the polypeptide which were disclosed in the '796 application, the '796 application teaches antibodies to the polypeptide, and the '796 application therefore anticipates the instant claims. Therefore, the rejection is maintained.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 7.1 Claims 40, 64, 88 and 112 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Deen et al., U.S. Patent No. 6,013,476, and further in view of Abrams et al., U.S. Patent No. 5,112,954, May 12, 1992.

Applicants traverse the rejection and assert that as discussed in the rejection under 35 U.S.C. 102(e), the '796 application of Deen et al. is unavailable as art under 35 U.S.C. 102 against the instant claims.

Applicants' arguments have been fully considered but are not deemed persuasive, for the reasons of record in the previous office action at pages 11-12 and for the reasons discussed above in the rejection under 35 U.S.C. 102(e).

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7.2

Claims 42, 43, 66, 67, 90, 91, 114 and 115 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Deen et al., U.S. Patent No. 6,013,476, and further in view of Chester et al.,

U.S. Patent No. 5,876,691, March 2, 1999.

Applicants traverse the rejection and assert that as discussed in the rejection under 35

U.S.C. 102(e), the '796 application of Deen et al. is unavailable as art under 35 U.S.C. 102

against the instant claims.

Applicants' arguments have been fully considered but are not deemed persuasive, for the

reasons of record in the previous office action at pages 13 and for the reasons discussed above in

the rejection under 35 U.S.C. 102(e).

7.3 Claims 34, 38, 39, 59, 62, 63, 82, 86, 87, 107, 110, 111 and 123 are rejected under 35

U.S.C. 103(a) as being unpatentable over Deen et al., U.S. Patent No. 6,013,476, and further in

view of Jakobovits et al. et al., U.S. Patent No.6,235,883, May 22, 2001.

Applicants traverse the rejection and assert that as discussed in the rejection under 35

U.S.C. 102(e), the '796 application of Deen et al. is unavailable as art under 35 U.S.C. 102

against the instant claims.

Applicants' arguments have been fully considered but are not deemed persuasive, for the

reasons of record in the previous office action at pages 14-15 and for the reasons discussed above

in the rejection under 35 U.S.C. 102(e).

#### Conclusion

#### 8. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM. Applicant is advised that effective January 23, 2003, the Examiner's phone number will be (571) 272-0878.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564. Applicant is advised that effective January 23, 2003, Yvonne Eyler's phone number will be (571) 272-0871.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

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Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

YVONNE EYLER, PH.D SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600